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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,895	02/04/2004	Rory F. Finn	32152	4167

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,895	FINN, RORY F.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/04/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Groups IX and X (Examiner has rejoined), a method of treating traumatic brain injury or subarachnoid hemorrhage (Examiner has rejoined) with a compound of FORMULA I, and the FORMULA I species wherein n is 4, m is 3, and R is hGH; in the reply filed on 08/22/06 is acknowledged. The traversal is on the ground(s) that a search of all the myriad diseases/disorders using a compound of formula I (or II) does not pose an undue burden. This is not found persuasive for the reasons of record, primarily the lack of overlapping or coextensive searching ability without an undue burden of all these unrelated, non-class diseases/disorders:

> The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper. Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

[It is noted that Applicant has elected a method of use, rather than the product (e.g. Group XXXXI). Under *In re Ochiai*, rejoinder of 'methods' is permitted, where a product is found allowable, and the methods are commensurate in scope (not the reverse, contrary to what Applicant appears to have asserted on page 3). Thus, the product claims 9-10 (e.g. formula I) are not subject to rejoinder]. Claims 9-10 are withdrawn (as well as claims 1-8 as to subject matter pertaining to formula II). Claims 1-8 are examined on the merits, as drawn to the elected method of treating traumatic brain injury or subarachnoid hemorrhage (Examiner has rejoined) with a compound of FORMULA I, and the FORMULA I species wherein n is 4, m is 3, and R is hGH.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 4 is objected to because of the following informalities: the claim is grammatically awkward, reading "hGH is having the structure of formula I with n equals 4 and m equals 3". Replacing "is having" with –has-- and "with" with --wherein--, may be an option for consideration. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I. Prevention

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inhibited growth related disorders (non-elected, which hGH is known to be used for) using a compound of formula I, does not reasonably provide enablement for *preventing* traumatic brain injury or subarachnoid hemorrhage, using the present compound formula I compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed (based on knowledge within the art, and the specification background) that the claimed compound formula I may be used for treating inhibited growth related disorders. However, the claims also encompass using the claimed compound formula I to prevent traumatic brain injury or subarachnoid hemorrhage, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as traumatic brain injury or subarachnoid hemorrhage (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition, which would

function to prevent traumatic brain injury or subarachnoid hemorrhage using a compound of formula I.

II. Treatment

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inhibited growth related disorders (non-elected, which hGH is known to be used for) using a compound of formula I; does not reasonably provide enablement for treating traumatic brain injury or subarachnoid hemorrhage, using the present compound formula I compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the latter method above.

The nature of the invention: The invention is discussed above.

The state of the prior art and the predictability or lack thereof in the art:

A very broad search of the prior art (EAST) database for the use of hGH in the same paragraph as traumatic brain injury or subarachnoid hemorrhage, using the present compound formula I compound, yielded only Applicant's present published specification (20040142870). A search of hGH even anywhere in the same reference with traumatic brain injury or subarachnoid hemorrhage produced no connection between the two, or enabled specification using hGH for the treatment of either (or even a reasonable assertion thereto). Thus, the prior art of record, either before or after Applicant's priority date, is lacking any reasonable assertion or enablement for the use of hGH to treat traumatic brain injury or subarachnoid hemorrhage.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). A search of Applicant's published specification produced only 2 passages directed to the use of hGH for the treatment (or prevention) or traumatic brain injury or subarachnoid hemorrhage (para 121, claim 1). Neither passage gave any indication of how hGH is able to treat (or prevent) traumatic brain injury or subarachnoid hemorrhage. There are no tests or examples as to the above.

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to the use of hGH compounds of formula I for the treatment of traumatic brain injury or subarachnoid hemorrhage. Both the specification and prior art of record lack any

reasonable basis as to whether hGH can treat either traumatic brain injury or subarachnoid hemorrhage. Absent teachings in the specification or art sufficient to overcome the inherent teachings of unpredictability in the art as to enablement on the use of hGH for traumatic brain injury or subarachnoid hemorrhage; it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

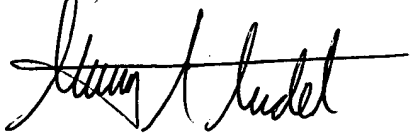
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 11/11/2006



MAURY AUDET
PATENT EXAMINER